

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MEMORANDUM

FROM: Warren Lux W. Jux

EPA Human Subjects Research Review Official

TO:

R. Julian Preston

Associate Director for Health, NHEERL

SUBJECT: Approval of Research Involving Human Subjects

DATE: August 23, 2011

I have reviewed the study cited below according to the requirements of EPA Order 1000.17 Change A1 (Policy and Procedures on Protection of Human Research Subjects) and have determined that it qualifies as observational research involving human subjects that complies with EPA Regulation 40 CFR 26 (Protection of Human Subjects). The finding of compliance includes the determination that the research is non-exempt under 40 CFR 26.101(b), that it has been approved by the IRBs of record, and that the institutions engaged in the research have valid Federalwide Assurances on file with the HHS Office for Human Research Protections. Accordingly, approval is granted for recruitment and enrollment of human research subjects into the study.

Study Title: An Epidemiologic Health Study of Manganese Exposure in

Adult Residents of East Liverpool, Ohio

Engaged Institutions: San Francisco State University

U.S. Environmental Protection Agency, National Health

and Environmental Effects Research Laboratory

FWA #s: FWA00006416 (SFSU)

FWA00012755 (U.S. EPA)

Principal Investigators: Rosemarie Bowler (SFSU)

Danelle Lobdell (U.S. EPA)

HSRRO Project #: H11-065CS

CC: Howard Kehrl Danelle Lobdell